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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,829	08/05/2005	Shai Amisar	4110-34	4361

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,829	Applicant(s) AMISAR ET AL.	
	Examiner Michael J. Anderson	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodicky (USPN 4,333,455). The patent to Bodicky discloses a catheter introducer system for introducing a catheter into a body passageway and delivering intravenous medicament to the patient.

In regards to claims 1 and 2, Bodicky ('455) discloses a multi-use port element (52) having a bore (58) and a hub (55) configured for transcutaneous positioning and liquid flow communication with a vein (figures 2 and 3), removable needle (60) from entry port element, needle hub (63). A flexible catheter tube (22) with a hub (26), an aperture (39) and a slide adaptor-connector (24) designed to allow catheter (22) slidable insertion through the port element into a vein of a patient (Figure 7 and Col. 4, lines 26-55).

In regards to claim 4, Bodicky ('455) discloses a second end of the cannula (52) formed with a taper (54) providing a compression lip seal for the catheter (22).

In regards to claims 5 and 7, Bodicky ('455) discloses a slide adaptor-connector and connector element (24) have a Luer Lock (Col. 3, lines 67-68 and Col. 4, lines 1-2).

In regards to claim 6, Bodicky ('455) discloses a catheter (22) with a connector element (26), removable cap (28 and 30), configured to connect to an intravenous therapeutic device (68, 168, 268, and 468), a slidable connector element (24) configured to connect with the entry port element (Col. 4, lines 26-55).

In regards to claim 8, Bodicky ('455) discloses an integral sterile environment containment element (20) enclosing the catheter (Col. 3, lines 48-58).

In regards to claim 12, Bodicky ('455) discloses a selectably operable locking device (Col. 4, lines 55-61).

In regards to claim 13, Bodicky ('455) discloses an entry-port element with a valve for regulating a flow of liquid through the catheter tube (figure 7 and No. 32).

In regards to claims 14 and 15, Bodicky ('455) discloses an intravenous cannula element, first and second ends and a bore formed therebetween configured for transcutaneous positioning. a self-contained sterile catheter apparatus, a first and second ends and a flexible catheter tube with a predetermined length therebetween, a connector element, removable cap, slidable-connector element, a diameter adapted for slidable insertion through said bore of said intravenous cannula element into the body organ of the subject, and an integral sterile environment containment element (Col. 3, lines 44-68 and Col. 4, 26-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky ('455) in view of Feller et al. (USPN 4,362,156).

Bodicky ('455) teaches the limitations of claims 1 and 2. However, concerning claims 3, Bodicky lacks mounting lugs to secure the catheter to the subject. Feller ('156) discloses entry-port element (10) with mounting lugs (60) to secure the entry-port element to the subject (66 and Col. 6, lines 20-24). Mounting lugs are well known in the art and thus it would have been obvious for one of ordinary skill in the art to modify Bodicky's catheter system with mounting lugs to secure catheters to a subject to

prevent unintended displacement and ensure continued access to the patient for reliable delivery of medicaments.

Claims 9-11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky ('455) in view of Gray et al. (USPN 6,086,008).

Bodicky ('455) teaches the limitations of claims 1, 8, and 14. However, concerning claims 9, 10, and 16, Bodicky lacks a cylindrical housing and an apparatus for introduction and withdrawal of a catheter from a coiled configuration. Gray ('008) discloses a cylindrical housing (18) with a withdrawable coiled catheter (2) and a clutch device to control forceful insertion of the catheter tube through the entry port into a vein (Col. 5, lines 24-31). It is well known in the art for the need to control the forceful insertion of a catheter into a subject and would have been obvious to one of ordinary skill in the art to combine Bodicky's coiled catheter with Gray's cylindrical housing to enable controlled forceful insertion of a sterile catheter into a patient..

Concerning claims 11 and 17, Bodicky lacks a removable stiffener element. Gray ('008) discloses a removable stiffener element (7). It would have been obvious to one of ordinary skill in the art to modify Bodicky's catheter system with Gray's stiffener element because stiffener elements or guidewires are well known in the art to aid in the placement of catheters within a vessel.

Response to Amendment

The present communication responds to the Amendment of 04/13/2007.

By this communication, claims 1, 2, 4, 6, 8 and 14-17 were amended and claims 18-21

were canceled. The amendments did not add new matter. Claims 1-17 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 8/6/2007 have been fully considered but they are not persuasive. Bodicky discloses a taper seal.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
10/15/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, appearing to read "Kevin C. Sirmons", is written over the printed name and title of the Supervisory Patent Examiner.